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Formulation and Evaluation of Fast Disintegrating Tablet of Cetirizine Hydrochloride

Mhaske Nilesh, Mishra Abhishek*, Pawar Rajeshwari, Nimase Abhishek, Mane Pooja and Pardeshi Shubham.

Department of Pharmaceutics, Dr.VithalraoVikhePatil Foundation's College of Pharmacy, ViladGhat, Ahmednagar, Maharashtra, India-414111

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ABSTRACT

The objective of this study was to develop and assess or evaluate fast-disintegrating tablets of cetirizine hydrochloride for the treatment of allergic rhinitis. The tablets were prepared using the direct compression method with different concentrations of disintegrating agents such as croscarmellose sodium and sodium starch glycolate. The tablets were evaluated for their various parameters like hardness, friability, weight variation, disintegration time, and drug release. The optimized batch was selected based on the highest percentage of drug release and shortest disintegration time. The optimized batch of cetirizine hydrochloride fast disintegrating tablets showed good flow properties, a rapid disintegration time of fewer than 50 seconds and a satisfactory drug release profile. The results suggest that fast-disintegrating tablets of cetirizine hydrochloride can be a promising dosage form for the treatment of allergic rhinitis.

Keywords: Cetirizine hydrochloride, Fast disintegrating tablet, Super disintegrants, Direct Compression.

I. INTRODUCTION

Despite the growing attention and interest in developing controlled release and targeted drug delivery systems, tablets that disintegrate and release medication quickly in the gastrointestinal tract after being swallowed whole are still the preferred option for manufacturing and patient acceptance. Therefore, tablets require dissolution before they can be absorbed and transported into the body's circulation. Patients often struggle to take tablets, which can lead to non-compliance and reduced effectiveness of treatment. Difficulties with swallowing can be a problem for patients of all ages but are especially common among the elderly, children, and those with psychiatric conditions. Despite these challenges, oral administration of medication remains the most favoured approach due to its simplicity in application, flexibility, convenience, and patient preference. Based on the considerations mentioned above, research focused on patient convenience and compliance has led to the development of safer and more advanced drug delivery systems. One such approach is the fast-disintegrating drug delivery system. Fast disintegrating drug delivery systems (FDDDS) are a modern type of medication that combines the benefits of both traditional tablet and liquid formulations while also providing additional advantages. These new formulations offer the convenience of tablets and the ease of swallowing liquid formulations. They allow for more precise dosing compared to liquid medications, which is a significant advantage. Novel drug delivery systems have made significant progress in recent times to improve the safety and effectiveness of medications while ensuring that patients continue to take them as prescribed. The ultimate goal is to enhance patient compliance with treatment regimens. The U.S. Food and Drug Administration's Center for Drug Evaluation and Research (CDER) has defined in an "orange book" Fast Disintegrating Tablets (F.D.T.s) as solid dosage forms that quickly break down, typically within seconds, when placed on the tongue. According to the European Pharmacopoeia, F.D.T.s are tablets without a coating that are meant to be placed in the mouth, dispersed rapidly and then swallowed. They should disintegrate within three minutes. Fast disintegrating tablets (F.D.T.) have various names such as mouth dissolving, fast dissolving, rapid-dissolving, orally disintegrating, rapid disintegrating, fast melt, orodispersible, rapid melt, melt-in-mouth and porous tablets. The effectiveness of drugs may be improved by their absorption in the oral cavity and the absorption of saliva containing the dispersed drugs before

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reaching the stomach. Additionally, the amount of drug that undergoes first-pass metabolism is lower compared to standard tablets. However, conventional dosage forms for the treatment of allergic and respiratory disorders, such as tablets, capsules and liquid dosage forms, can have drawbacks such as difficulty in swallowing and delayed onset of action due to slow dissolution rate. The liquid dosage form does not comply with stability and measurement. Good bioavailability, improved patient compliance, good stability, and rapid onset of action make fast-disintegrating tablets different from other dosage form in the market. Cetirizine Hydrochloride is a second-generation antihistamine drug used to treat various allergic conditions such as seasonal and perennial allergic rhinitis, chronic urticaria, and atopic dermatitis. It is also used in seasonal asthma as an adjuvant and allergic cough. Cetirizine inhibits the release of histamine and other allergic response mediators. Patients with sore throat conditions may find it difficult to swallow tablet forms of the drug, making fast-disintegrating tablets a more suitable option. This is especially beneficial for paediatric patients who have difficulty swallowing conventional tablets and capsules. The primary goal of the article is to present a comprehensive summary of the formulation and evaluation of F.D.T.s of cetirizine hydrochloride, highlighting the key considerations in the development of such formulations. The article also discusses the potential advantages of F.D.T.s of cetirizine hydrochloride and their suitability for patient populations with swallowing difficulties or those requiring fast relief of symptoms. [1,2,3]

II. METHODOLOGY

Materials:

Cetirizine hydrochloride was purchased from Dolphin Pharmacy, Mumbai.Microcrystalline Cellulose (Avicel PH 102) and Mannitol was purchased fromModern Industries, Nashik.Croscarmellose Sodium, Magnesium Stearate, Talc and Aspartame was purchased from Loba Chemicals, Mumbai. Mint Flavour was purchased from S.D Fine Chem Ltd, Mumbai. Analytical grade chemicals and reagents were exclusively utilized for all other purposes.

Methods:

Preformulation Study of Drug and Excipients[4,5,6,12]

Preformulation studies involve the examination of the physical and chemical characteristics of a drug substance both in its pure form and when combined with excipients. These studies serve as an initial stage in the systematic development of a drug formulation. The main goals of pre-formulation studies are to gather a comprehensive set of data about the drug substance. These investigations aim to identify the physicochemical properties of the drug substance and the excipients that can potentially impact the formulation design, manufacturing process, and pharmacokinetic and biopharmaceutical properties of the final product. The formulation studies encompass a range of analyses and evaluations.[11,12]

1. **OrganolepticProperties:** This involves documenting the colour, odour, and Taste of the new drug using descriptive terminology. Keeping a record of the colour of initial batches is valuable in determining suitable specifications for future production. Drugs typically possess distinctive odours and tastes, with any unpleasant characteristics being masked during the formulation process.
2. **Solubility:** Solid drugs taken orally need to dissolve in the fluids of the gastrointestinal tract before they can be absorbed and exert their systemic effects. Therefore, the rate at which drugs dissolve can impact the speed and extent of their absorption into the body. The solubility of the drugs was investigated at a temperature of 37°C.
3. **MeltingPoint:** The melting point of a drug is a significant parameter for its identification and characterization. To determine the melting point, a digital method was employed. The drug sample was placed in a Thiele tube, with one end sealed using a flame. This tube, containing the drug, was immersed in liquid paraffin within a melting point apparatus. The observed melting point served as an initial indicator of the sample's purity, as the presence of even a small amount of impurity can cause a decrease or broadening in the melting point range.
4. **U.V-Visible Spectroscopy Analysis:**The absorbance maxima that have been specified are determined by using U.V. The methods for preparation of the Reagents and Standard stock solution are as follow:

a) **Preparation of 0.1n HCl solution:**Take 8.5 ml of Hydrochloric acid anddissolve it in 1000 ml of distilled water [13]

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b) **Preparation of Standard Stock Solution:**TheU.V. scanning of the drug samplewascarriedoutusing a solutionofthe drugdissolvedin0.1n HCl; theλ_{max}wasobservedat231nm.Cetirizine Hydrochloride 10 mg was accurately weighed and dissolved separately in 0.1n HCl solution. Shake and sonicate itfor 20 min. Adjustthe finalvolume to100mlwith 0.1n HCl solution to get a concentration of 1000 µg/ml. 1 ml of theabove-prepared solutions was further separately diluted to 10 ml to get a concentration of 10µg/ml ofCetirizine Hydrochloride.Thesewereused asstock solutions.

c) **Preparationof Calibration Curve:**From the respective stock solution (100 µg/ml), different concentrations of 5, 10, 15, 20, 25 and 30 µg/ml. Cetirizine Hydrochloride was prepared and scanned in the U.V. region. Cetirizine Hydrochlorideabsorbance was noted at their above-selected respective λ_{max}, a calibration curvewasplottedasabsorbancevsconcentration, andtheirlinearityrangewasdetermined.

d) **ScanningSolution:**The solution containing 10ug/ml of Cetirizine Hydrochloride in 0.1n HCl was scanned over the range of 400-200nmagainst0.1n HCL solutionatdifferent pH asblankusingUV-VisibleSpectrophotometer (Jasco, Tokyo).The$\lambda_{max}$for the puredrugwas thendetermined.

5. **Infrared Spectroscopy Analysis:** The infrared spectra of pure Cetirizine Hydrochloride were recorded by Fourier Transformed Infrared Spectrophotometer (Jasco, Tokyo). They are directly placed on the lesser pointand examined in the transmission mode. Spectrum was measured over a frequency range of 4500–500 cm^{-1}. The peaks obtained in the spectra were then compared withcorrespondingfunctionalgroups inthestructuresof Cetirizine Hydrochloride.

Evaluation of granules[13]

The following parameters are determined.

1. **Angleof Repose:**The angle of repose for the granules was determined using the funnel method. The granules were accurately weighed and placed in a funnel. The height of the funnel was adjusted so that its tip touched the top of the granule heap. The granules were then allowed to flow freely through the funnel onto the surface. The diameter of the resulting powder cone was measured, and the angle of repose was calculated using the provided equation:

Tan θ = h/r

Where,handr arethe heightandradiusof thepowder cone, respectively.

2. **Bulk density:** Both loose bulk density (LBD) and tapped bulk density (TBD.) were determined. A quantity of 3.64 g of powder from each formula, is incorporated into bulk density apparatus (Electrolab, ETD-1020).After the initial volume was observed, the cylinder was allowed to fall under its ownweight onto a hard surface from the height of 2.5 cm at 2-second intervals. Thetapping was continued until no further change in volume was noted. LBD and T.B.D. were calculated using the following formulas:

LBD= Weight of the Powder/Volume of packing

TBD=Weight of the Powder/Tapped volume of packing

3. **Carr's Compressibility Index:** The compressibility index of the granules was determined by Carr's compressibility index.

$$\text{Carr'sindex}(\%)=\frac{\textbf{Tapped Density} - \textbf{Bulk Density}}{\textbf{Tapped Density}} \times \mathbf{100}$$

4. **Hausner'sRatio:** Hausner'sratioisanumerical value that is correlatedtotheflowability characteristics of granular powder material.

$$\text{Hausner'sratio}= \frac{TD}{BD}$$

Method of Preparation:

Fast disintegrating tablet of Cetirizine hydrochloride was prepared by direct compression method. It involves mixing of drug with different excipients in a specific ratio. The concentration of Croscarmellose Sodium which is incorporated as super disintegrants varies in the formulation from F1 to F6 in order to achieve the optimized batch. A batch of 110 tablets, each weighing 300 mg is formulated.[11]

Sifting: The drug, along with other excipients, as mentioned in Table No. 1ispassedthrough Sieve no.60.

Mixing: All the ingredientsifted wasmixed completelyin amortar.

Compression: The lubricated mixture was compressed by using 8-station tablet compression machines (Labpress Machinery Co. Ahmedabad, India).

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Table No. 1: Formula for 1 Tablet (300 mg) for F1-F6 formulation.

Sr.No.	Composition	F1	F2	F3	F4	F5	F6
1	Cetirizine Hydrochloride(mg)	5	5	5	5	5	5
2	Croscarmellose Sodium(mg)	3 (1%)	6 (2%)	12 (4%)	18 (6%)	24 (8%)	30 (10%)
3	Microcrystalline cellulose (mg)	5	5	5	5	5	5
4	Magnesium Stearate(mg)	4	4	4	4	4	4
5	Talc (mg)	2	2	2	2	2	2
6	Aspartame (mg)	8	8	8	8	8	8
7	Mint Flavour (mg)	8	8	8	8	8	8
8	Mannitol(mg)	265	262	256	250	244	238

EvaluationofTablet: [7,8,9,10,11,14]

1. GeneralAppearance.
2. Thickness.
3. Hardness.
4. Friability.
5. WeightVariationTest.
6. Content Uniformity
7. InvitroDisintegrationTime.
8. InvitroDrugRelease.
9. Stability Studies.

1. **GeneralAppearance:**General appearance encompasses various factors, including size, shape, colour,odour, taste, texture, legibility, and identifying marks.
2. **Thickness:** Crown size can be measured using a micrometre, while a sliding calliper scale is used to measure the size of multiple tablets (5 to 10) simultaneously.At the laboratory level, tablet size is measured using a Vernier calliper (Omega Instruments Ltd.).Controlling tablet thickness within a ±5% variation of a standard value is important.
3. **Hardness:**The hardness of each formulation's tablet is determined using the Monsanto hardness tester (Dolphin). The tablet is placed between the two jaws of the tester, held along its oblong axis. Initially, the reading should be zerokg/cm^2.By rotating the knob, a constant force is applied until the tablet fractures. The value recorded at this point represents the tablet hardness in kg/cm^2.
4. **Friability:** Twenty tablets were rotated in a Roche Friabilator (Electolab) at 25 rpm for 4 min. Thetablets were then deducted, and the loss in weight due to fracture or abrasion wasrecordedas percentageweight loss (% friability)

% Friability = Initial Weight – Final Weight/ Initial Weight X 100

5. **Weight Variation Test:** It involves selection of twenty tablets and measuring their weight using a digital weighing balance (Shimadzu). The average weight of the tablets was calculated. Subsequently, each tablets weight was measured individually and compared to the average weight as indicated in Table no. 2.

Table No. 2: Official Standard Limits for Weight Variation as per I.P.

AverageweightofTablet(mg)	MaximumPercentagedifference allowed
80	10%
80-250	7.5%
>250	5%

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6. **Content uniformity:** In this test, a sample of 30 tablets is randomly selected, and at least 10 are assayed individually. Nine of the 10 tablets must contain not less than 85% or more than 115% of the labelled drug content. The tenth tablet may not contain less than 75% or more than 125% of the labelled content. If these conditions are not met, the tablets remaining from the 30 must be assayed individually, and none may fall outside of the 85 to 115% range.

Thirty tablets of each product were crushed into a fine powder, and an amount equivalent to one tablet was transferred with precision into a 100 mL volumetric flask. 70 mL of water was then added to each flask, and the contents were shaken for 15 minutes using a temperature-controlled shaking water bath set at 37°C. The volume was then made up to the mark with water, and the solution was mixed thoroughly before being filtered. The filtrate was diluted with water to an appropriate concentration, and the absorbance of the resulting solution was measured using a UV-Visible spectrophotometer (Jasco, Tokyo) at the predetermined wavelength (λ_{max}) of 231 nm for Cetirizine HCl.

7. **In vitro disintegration time:** The in vitro disintegration time was measured using the apparatus described in the U.S.P (Veego Disintegration Apparatus). Distilled water was used as the disintegration medium, with a volume of 900 ml. The temperature was maintained at 37±0.2°C. The duration required for the tablet to fully dissolve, leaving no detectable residue in the apparatus, was recorded in seconds.

8. **In vitro Drug Release Study:** The in vitro dissolution study of the developed Cetirizine Hydrochloride fast-dissolving tablets was conducted using U.S.P. apparatus Type-II (Electrolab, TDT-06T, Mumbai). The tablets were immersed in 900 ml of 0.1n HCl buffer solution at a temperature of 37°C ± 0.5°C while being rotated at a speed of 100 rpm. At 5-minute intervals during the test, 5 ml samples of the dissolution medium were withdrawn. These samples were then analyzed using a UV/Visible spectrophotometer (Jasco, Japan) at a wavelength of 231 nm. To maintain the volume, an equal amount of fresh dissolution medium at the same temperature was added after each sample withdrawal. The absorbance values obtained were converted to concentrations using a standard calibration curve established through experimental means.

TableNo.3:DissolutionStudyParameter

Parameters	Conditions
Dissolutionmedia	900ml of 0.1nHCl
Temperature	37 ± 1^0C
RPM	100
DrugContent	Weighof the tablet is equivalent to5 mg
VolumeWithdrawn	5ml
Volumemadeup to	10ml
λ_{max}	231 nm
DilutionFactor	2

9. **Stability Studies:** Stability studies were conducted according to the ICH guidelines. The prepared medicated were kept at three different temperatures. The first formulation was kept at room temperature, the second formulation was kept in cold temperature and the third formulation was kept in the stability chamber at a temperature of 40° C/75 % RH for 3 months. At the end of 3 months, samples were with drawn and observed for physical appearance and investigated for % drug release.

III. RESULT AND DISCUSSION

1. **Preformulation of Drug:**

a) **Determination Melting Point:**The melting point was observed by the digital melting point apparatus (Veego Melting Point Apparatus).Themeltingpointswerefoundto be in the rangeof223°C-231°C (225°C).

b) **Organoleptic Properties of Drug and Solubility:**

- **Colour:** White to off-white.
- **Odour:** Odourless.
- **Taste:** Slightly Bitter.
- **State/Form:** Non hygroscopicPowder.

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- **Solubility:** Soluble in organic solvents such as ethanol and sparingly soluble in water.

c) CalibrationCurveofCetirizine: Table no.4 describes the parameters of Calibration Curve and Fig no. 1 depicts the maximum wavelength (λ_{max}) of Cetirizine HCl. Table no.5 provides the concentrations and corresponding absorbance values of Cetirizine HCl. The plot in Figure No. 2 displays the relationship between concentration and absorbance.The solutions demonstrated compliance with Beer-Lambert's Law within the concentration range of 2 to 10 µg/ml, achieving a high regression coefficient (R^2) of at least 0.999. The regression equation for Cetirizine HCl was y = 0.0247x + 0.1631. This equation was utilized to determine the in vitro drug release of different Cetirizine HCl formulations.

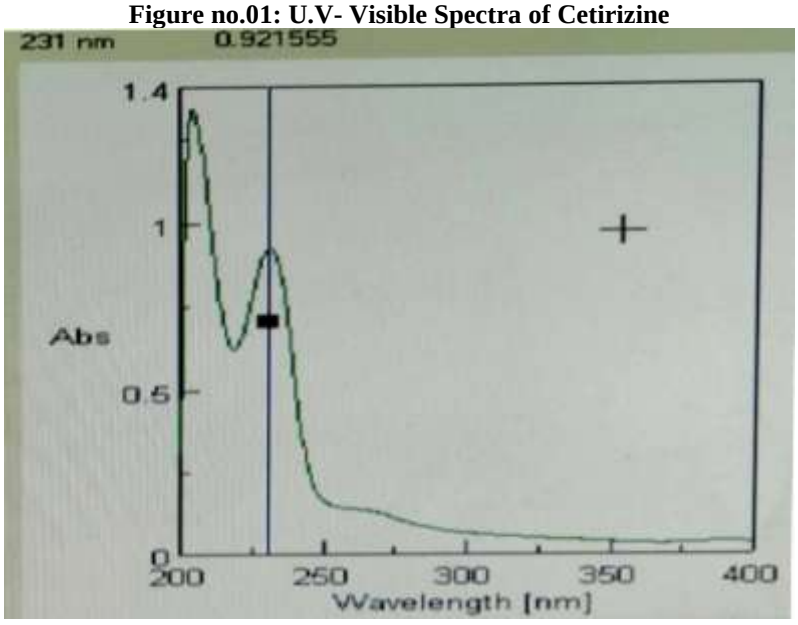
Table No.4: U.V-Visible Parameter for calibration curve in 0.1n HCl

Sr.No.	Parameters	Values in 0.1nHCl
1	Absorbance maximum (λ_{max}) in nm	231 nm
2	Slope	0.0247
3	Intercept	0.1631
4	Regression Coefficient	0.999
5	Equation	Y= 0.0247x + 0.1631

TableNo.5:Absorbance of Cetirizine

Sr.No.	Conc(mg/ml)	Absorbance(nm)
1	0	0
2	5	0.295
3	10	0.4006
4	15	0.5293
5	20	0.6595
6	25	0.7893
7	30	0.9012

Figure no.01: U.V- Visible Spectra of Cetirizine



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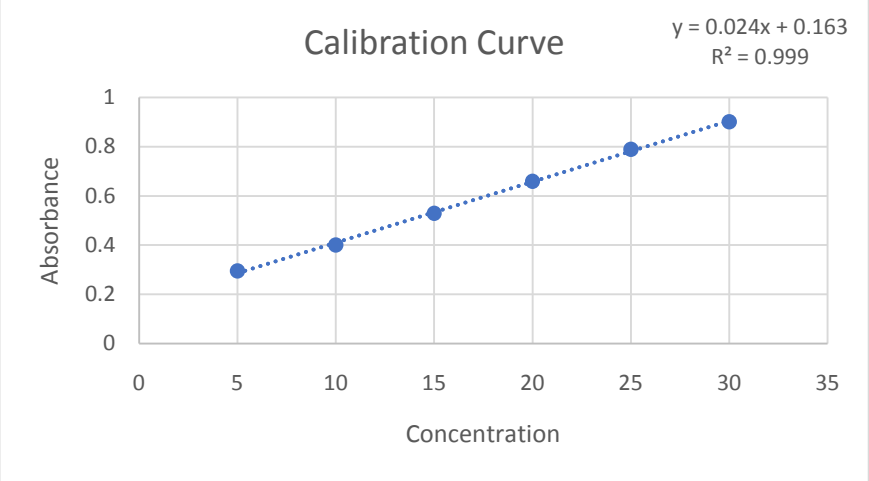
Figureno.02: Standard CalibrationCurve



d) Infrared Spectroscopy Study: The FTIR spectrum of Cetirizine hydrochloride shows a distinctive absorption peak forat 1184.08 cm^{-1}, 1312.32 cm^{-1}, 1055.84 cm^{-1}, 757.88cm^{-1}which corresponds to the presence of functional group such as Tertiary amine, Carboxylic acid, Alkyl substituted ether and Aliphatic chlorocompound. The FTIR spectrum of Cetirizine hydrochloride and excipients shows a distinctive absorption peak forat1182.15 cm^{-1}, 1316.18 cm^{-1}, 1056.8 cm^{-1}, 757.88cm^{-1}which indicates no change in the functional group such as Tertiary amine, Carboxylic acid, Alkyl substituted ether and Aliphatic chlorocompound confirming no changes or disturbance in the structure of Cetirizine hydrochloride, indicates no drug-excipient interaction as shown in Figure no. 3 and Figure no. 4.

Figureno. 03: I.R. Spectra of Cetirizine

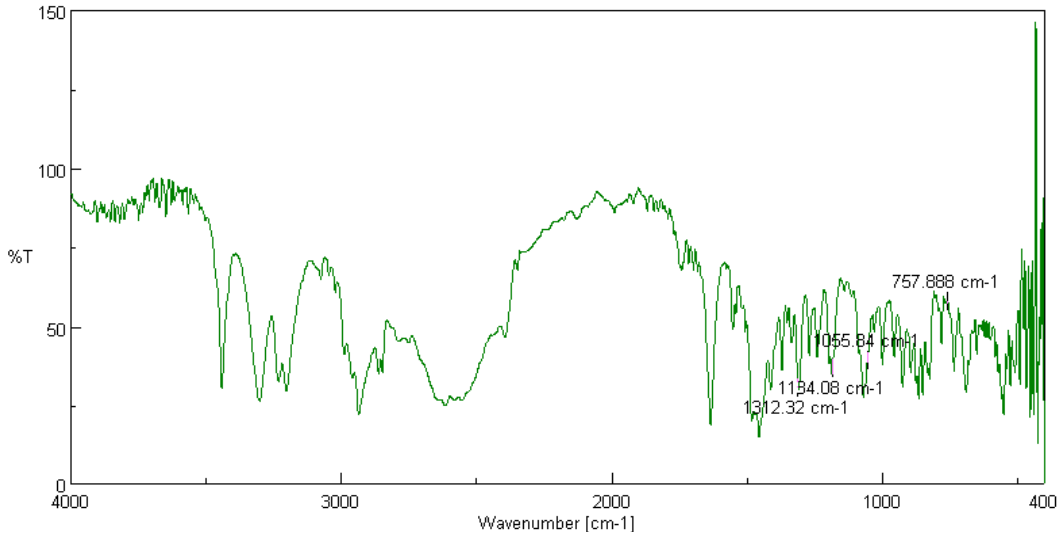


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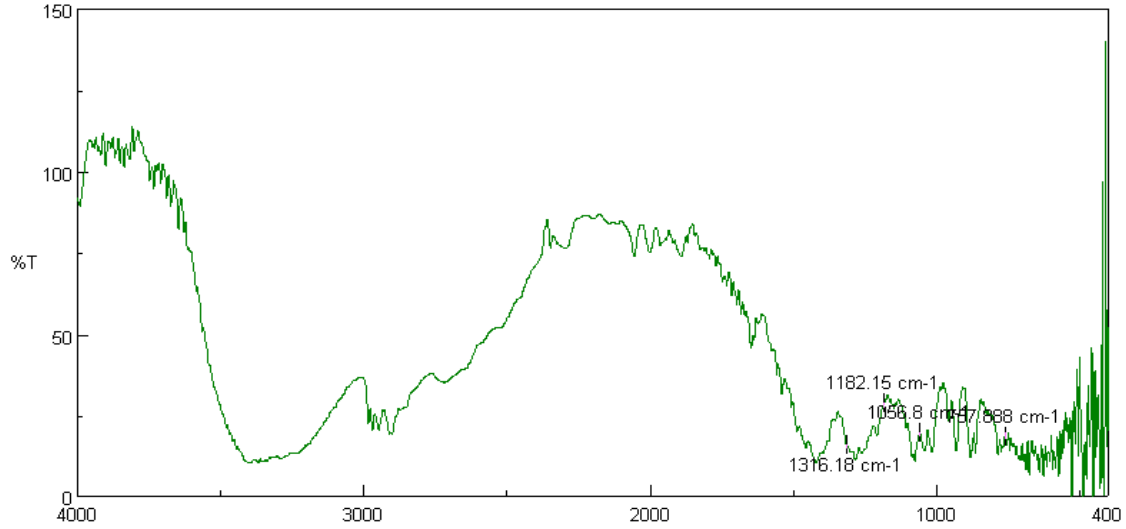
Figure no.04: IR Spectra of Cetirizine with excipients



2. **Evaluation of Powder:** The pre-compression variables of the fast-dissolving tablets prepared through the direct compression method were assessed, including bulk density, tapped density, Hausner's ratio, compressibility percentage, and angle of repose. The corresponding values are presented in Table No. 06. The bulk density ranged from 0.402 to 0.417 gm/cm^3, tapped density ranged from 0.485 to 0.513 gm/cm^3, the compressibility percentage ranged from 16.70% to 18.71%, and the angle of repose ranged from 26°18 to 32°.61. Based on these results, it can be concluded that all the powder blends exhibited favourable flow properties, making them suitable for the preparation of fast dissolving tablets using the direct compression method.

Table no. 06: Preformulation Parameter

Sr.No.	Formulation	Bulk Density(gm/cc)	Tapped density(gm/cc)	Carr's Compressibility (%)	Hausnersratio	Angle of Repose (Degree)
1	F1	0.414	0.503	17.69	1.21	29.82
2	F2	0.407	0.497	18.10	1.22	26.18
3	F3	0.404	0.485	16.70	1.20	32.61
4	F4	0.411	0.501	17.96	1.21	27.08
5	F5	0.402	0.496	18.95	1.23	31.28
6	F6	0.417	0.513	18.71	1.23	27.43

3. **Evaluationoftablet:**

a) **Organoleptic characters of tablet:** The organoleptic properties of tablet is given in Table no. 07.

Table no. 07: Organoleptic Property

Formulation	Colour	Odour	Shape
F1	White	Aromatic	Round
F2	White	Aromatic	Round
F3	White	Aromatic	Round
F4	White	Aromatic	Round
F5	White	Aromatic	Round
F6	White	Aromatic	Round

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b) Evaluation Parameter of tablets: The result of the evaluation parameters of tablet is given in Table no. 08.

Table no. 08: Evaluation Parameter

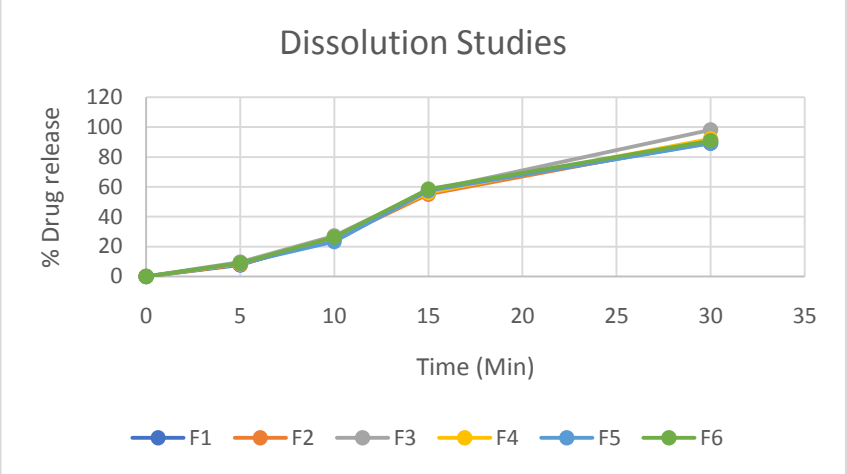
Formulation	Weight Variation	Thickness (mm)*	Hardness (Kg/Cm^2) *	Friability (%)	Disintegration Time (Sec)**	Drug Content Uniformity (%)
F1	Passes	3.4	2.9	0.5	83	91.98
F2	Passed	3.5	2.2	0.1	52	98.60
F3	Passed	3.5	3.1	0.3	48	99.94
F4	Passed	3.65	3.0	0.8	134	90.97
F5	Passed	3.5	2.8	0.1	92	93.60
F6	Passed	3.5	2.6	0.1	67	99.40

c) Dissolution Studies (% drug release): The direct compression method was used to prepare formulations with superdisintegrants, and their drug release was evaluated using a dissolution apparatus. The results are presented in Table no 09, and the corresponding graph is shown in Figure no.05The analysis revealed that the maximum drug release was achieved with 12 mg of Croscarmellose sodium, formulation F3, which exhibited a drug release of 98.23% within 30 minutes. Therefore, F3 was identified as the optimized formulation among all the formulations tested.

Table no. 09: Dissolution Study

Time(min)	F1	F2	F3	F4	F5	F6
0	00	00	00	00	00	00
5	07.66	8.24	09.61	8.59	8.86	9.04
10	26.62	25.04	27.25	26.11	23.39	26.41
15	56.89	55.09	57.42	56.06	57.34	58.52
30	89.47	90.62	98.23	92.17	89.08	90.94

Figureno.05: Drug release profile of Cetirizine hydrochloride



d) Stability Test: The prepared medicated tablets were kept at three different temperatures. The first formulation was kept at room temperature, the second formulation was kept in cold temperature and the third formulation was kept in the stability chamber at a temperature of 40° C/75 % RH for 3 months. At the end of 3 months, samples were withdrawn and observed for physical appearance and investigated for % drug

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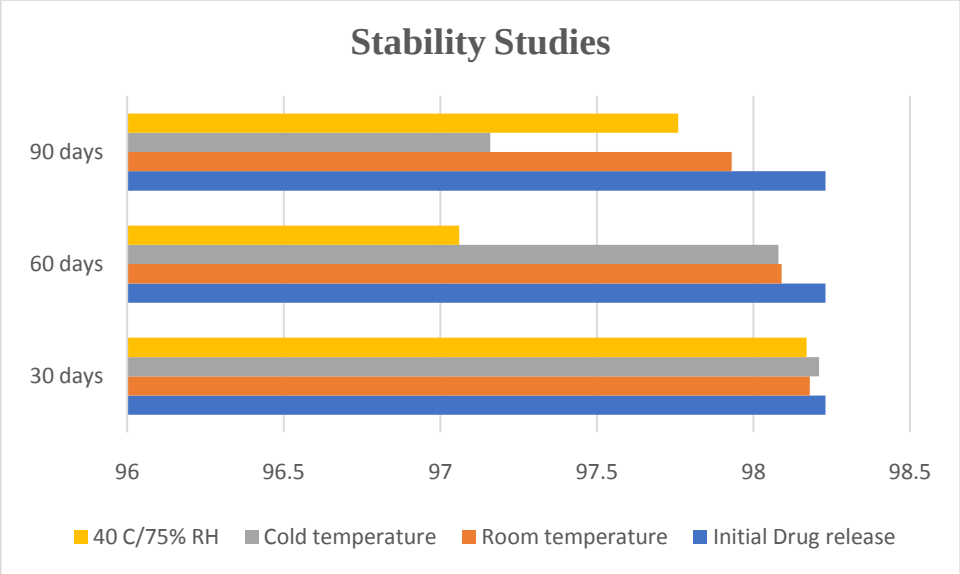
release. The data achieved by performing stability study is included in Table no. 10 and its graph for comparison is in Figure no. 6

Table no. 10: Stability Study

Formulation Code	Duration	Physicalappearance	Percentageofdrugrelease (%)			
			Initial Drug release	Room temperature	Coldtemperature	40^0C/75%RH
F3	30 Days	Nochange	98.23	98.18	98.21	98.17
F3	60 Days	Nochange	98.23	98.09	98.08	97.06
F3	90 Days	Nochange	98.23	97.93	97.16	97.76

Figure no.06: Stability Profile at Various Conditions



IV. DISCUSSION:

The present study utilized Cetirizine to create orodispersible tablets, utilizing available synthetic superdisintegrants for formulation. The evaluation process revealed that the superdisintegrants differed in their ability to disintegrate the Cetirizine orodispersible tablets based on their concentration. Superdisintegrants are often used to improve the dissolution of active pharmaceutical ingredients in solid dosage forms or to develop orodispersible tablets. In this study, three different concentrations of superdisintegrants were used (03 mg, 06 mg, 12 mg, 18 mg, 24 mg and 30 mg), and the results indicated that the drug and excipient were compatible, as confirmed through a drug compatibility study using FTIR spectrophotometry. The orodispersible tablets had a hardness of 2.6 kg/cm² to 3.1kg/cm², a thickness of 3.4mm to 3.6mm, and passed standard limits for percentage friability and weight variation. Among the formulations studied, formulation F3 showed the highest drug release, releasing 98.23% of the drug in 30 minutes. The powder blend was evaluated using various tests, including bulk density, tapped density, compressibility index, Hausner's Ratio, and Angle of Repose, and all values were within the specified limits, indicating it was suitable for direct compression. Evaluation tests, including weight variation, hardness, friability, thickness, disintegration time, and in vitro drug release studies, were carried out, and the F3 formulation showed the lowest disintegration time and highest drug release, making it the optimized formulation. The study concluded that 12 mg of Croscarmellose Sodium could be effectively used as a superdisintegrants to release Cetirizine for a short period of time.

STATEMENT OF ETHICS

We confirm that we have read and understood the Journal's position on issues involved in ethical

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publication and affirm that this report is consistent with those guidelines.

CONFLICT ON INTEREST

None

AUTHOR CONTRIBUTIONS

Idea/Concept: Nilesh Mhaske, Abhishek Mishra, Data Collection/Processing: Abhishek Mishra, Rajeshwari Pawar, Pooja Mane, Practical Analysis and Formulation: Abhishek Nimase, Rajeshwari Pawar, Abhishek Mishra, Literature Review: Nilesh Mhaske, Abhishek Mishra, Drafting/Writing: Abhishek Mishra, Shubham Pardeshi, Critical Review: Nilesh Mhaske, Rajeshwari Pawar.

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